APPENDIX B:

REGULATIONS FOR THE CONDUCT OF HUMAN RESEARCH

COMMONWEALTH OF VIRGINIA
BOARD OF HEALTH
12 VAC 5-20-10

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REGULATIONS FOR THE CONDUCT OF HUMAN RESEARCH

PART I: GENERAL PROVISIONS

1.1 Definitions

The following words and terms, when used in these regulations, shall have the following meanings, unless the context clearly indicates otherwise:

"Affiliated with the institution" means employed by or contracting with the institution or directly or indirectly involved in the management thereof.

"Commissioner" means the Commissioner of the Department of Health.

"Committee" means human research committee assembled pursuant to 12VAC5-20-70 of this chapter by any institution defined herein.

"Department" means the Department of Health.

"Human research" means any systematic investigation utilizing human participants who may be exposed to physical or psychological injury as a consequence of participation and which departs from the application of established and accepted therapeutic methods appropriate to meet the participants' needs.

"Informed consent" means the knowing and voluntary agreement, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion, of a person who is capable of exercising free power of choice. For the purposes of human research, the basic elements of information necessary to such consent shall include:

A. A reasonable and comprehensible explanation to the person of the proposed procedures or protocols to be followed, their purposes, including descriptions of any attendant discomforts, and risks and benefits reasonably to be expected;

B. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the individual;

C. An instruction that the person may withdraw his consent and discontinue participation in the human research at any time without prejudice to him;

D. An explanation of any costs or compensation which may accrue to the person and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols; and

E. An offer to answer any inquiries by any individual concerning the procedures and protocols.

In addition to the required elements, the information provided to the individual should also include the following:

A. A statement that the study involves research, and an explanation that includes identification of any procedures which are experimental; the expected duration of the individual's participation; and a

statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained; and if any data from this study are published, the individual will not be identified without his written permission;

B. A statement that there may be other risks not yet identified;

C. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the individual;

D. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled, and the individual may discontinue participation at any time without penalty or loss of benefits to which he is otherwise entitled;

E. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury; and

F. For research involving more than minimal risk, an explanation as to whether any compensation or medical care is available if injury occurs and, if so, what is included or where further information may be obtained.

Information should be provided in a manner that is understandable to the individual with regard to his educational level and language of greatest fluency.

"Institution" or "agency" means any facility, program, or organization owned or operated by the Commonwealth, by any political subdivision, or by any person, firm, corporation, association, or other legal entity.

"Legally authorized representative" means the parent or parents having custody of a prospective participant, the legal guardian of a prospective participant or any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective participant to such person's participation in the particular human research. For the purposes of this chapter, any person authorized by law or regulation to consent on behalf of a prospective participant to his participation in the particular human research shall include an attorney-in-fact appointed under a durable power of attorney, to the extent the power grants the authority to make such a decision. The attorney-in-fact shall not be employed by the person, institution or agency conducting the human research. No official or employee of the institution or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.

"Minimal risk" means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

"Nontherapeutic research" means human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the participant.

1.2 Applicability

This chapter shall apply to the department, including any local health department and to any facility operated, funded or licensed by the department which conducts or which proposes to conduct or authorize research which uses human participants.

1.3 Policy

A. No human research may be conducted without informing the participant or his legally authorized representative of the procedures, risks, and discomforts of the research. The consent of the participant or his legally authorized representative to participate in the research shall be subscribed to in writing by the participant or his legally authorized representative and supported by the signature of a witness not involved in the conduct of the research, except as provided for in 12VAC5-20-100 F and H of this chapter. Special arrangements shall be made for those who need assistance in understanding the consequences of participating in the research.

B. Each human research activity shall be reviewed and approved by a committee as set forth in 12VAC5-20-70 of this chapter composed of representatives of varied backgrounds who shall assure the competent, complete, and professional review of human research activities.

C. Every person engaged in the conduct of human research or proposing to conduct human research shall associate himself with an institution or agency having a research review committee, and the human research which he conducts or proposes to conduct shall be subject to review and approval by such committee in the manner set forth in these regulations.

D. Nontherapeutic research using patients or residents within an institution as defined herein is forbidden unless it is determined by the research review committee that such nontherapeutic research will not present greater than minimal risk.

E. The individual conducting the research shall be required to notify all participants of research of the risks caused by the research which are discovered after the research has concluded. If consent has been obtained by the signature of the legally authorized representative, the legally authorized representative shall also be notified.

PART II: THE REVIEW PROCESS

2.1 For the Department

A. Prior to the initiation of a human research project by any component of the department, a description of the proposed human research project shall be submitted to a research review committee established by the department for review and approval. The description shall include a statement of the purpose of the proposed project and justification thereof, the criteria for inclusion of a participant in the research project, a description of what will be done to the participants, and a copy of the informed consent statement.

B. The committee shall report by January 31 of each year to the commissioner on activities of the committee during the previous calendar year. Such reports shall include:

1. A description of each human research project reviewed and approved or disapproved;

2. Any significant deviations from proposals as approved;

3. A list of committee members, their qualifications for service on the committee, and their institutional affiliation; and

4. A copy of the minutes of any committee meetings conducted.

C. The chairman of the committee shall report as soon as possible to the commissioner any violation of the research protocol which led the committee to either suspend or terminate the research.

D. The commissioner may inspect the records of the committee.

E. The commissioner shall report at least annually to the Governor and General Assembly on the human research projects conducted by any component of the department as annually reported to the commissioner by the committee.

2.2 For Institutions or Agencies Funded or Licensed by the Department

A. Prior to the initiation of a human research project by any institution or agency funded or licensed by the department, a description of the proposed human research project shall be submitted to a research review committee for review and approval. The description shall include a statement of the purpose of the proposed project and justification thereof, the criteria for inclusion of a participant in the research project, a description of what will be done to the participants, and a copy of the informed consent statement.

B. When more than one such institution or agency is involved in a research project, the cooperating entities may enter into joint review.

C. Such institutions or agencies having a committee shall report by January 31 of each year to the commissioner on activities of the committee during the previous calendar year. Such reports shall include:

1. A description of each human research project reviewed and approved or disapproved;

2. Any significant deviations from proposals as approved;

3. A list of committee members, their qualifications for service on the committee, and their institutional affiliation; and

4. A copy of the minutes of any committee meetings conducted.

D. The chairman of the committee shall report as soon as possible to the head of such institution or agency and to the commissioner any violation of the research protocol which led the committee to either suspend or terminate the research.

E. The commissioner may inspect the records of the committee.

F. The commissioner shall report at least annually to the Governor and General Assembly on the human research projects conducted by such institutions or agencies as annually reported to the commissioner by the relevant research review committees.

PART III. THE RESEARCH REVIEW COMMITTEE

3.1 Composition

A. Each committee shall have at least seven members, appointed by the head of the institution, with varying backgrounds to provide complete and adequate review of activities commonly conducted by the institution. The committee shall be sufficiently qualified through the maturity, experience, and diversity of its members, including consideration of race, gender and cultural background, to promote respect for its advice and counsel in safeguarding the rights and welfare of participants in human research. In addition to possessing the professional competence necessary to review specific activities, the committee shall be able to ascertain the acceptability of applications and proposals in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes. If a committee regularly reviews research that has an impact on patients or residents within an institution as defined herein or other vulnerable category of participants, the committee shall have in its membership one or more individuals who are primarily concerned with the welfare of these participants and who have appropriate experience to serve in that capacity.

B. No committee shall consist entirely of members of one profession, and at least one member must be an individual whose primary concerns are in nonscientific areas (e.g., lawyers, ethicists, members of the clergy).

C. Each committee shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

D. No member of a committee shall participate in the committee's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the committee. The committee has responsibility for determining whether a member has a conflicting interest. The committee size shall be maintained at no fewer than seven persons by appointment of a substitute representative for each member with a conflicting interest.

E. A committee may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the committee. These individuals may not vote with the committee.

F. A quorum of the committee shall consist of a majority of its members including at least one member whose primary concerns are in nonscientific areas.

G. The committee and the institution shall establish procedures and rules of operation necessary to fulfill the requirements of this chapter.

3.2 Elements of the Committee Review Process

A. No human research shall be conducted or authorized by the institution or agency unless a research

review committee has reviewed and approved the proposed human research project giving consideration to:

1. The necessity and utility of the research;

2. The adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the research;

3. The degree of the risk, and, if the research is nontherapeutic, whether it presents greater than minimal risk;

4. Whether the rights and welfare of the participants are adequately protected;

5. Whether the risks to the participants are outweighed by the potential benefits of the research to them;

6. Whether the voluntary informed consent is to be obtained by methods that are adequate and appropriate to the individual's educational level and language of greatest fluency;

7. Whether the written consent form is adequate and appropriate in both content and wording for the particular research and for the particular participants of the research relative to their educational level and language of greatest fluency and whether the consent document reasonably reflects full explanation and adequate understanding;

8. Whether the persons proposing to supervise or conduct the particular human research are appropriately competent and qualified; and

9. Whether criteria for selection of participants are equitable, especially in research regarding the future development of mental or physical illness.

B. The committee shall consider research proposals within 45 days after submission to the committee. In order for the research to be approved, it shall receive the approval of a majority of those members present at a meeting in which a quorum exists. A committee shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure committee approval.

C. During the committee review of research projects, no personal identifiers of present or potential participants should be stated.

D. The committee shall approve or develop a written description of the procedure to be followed when a participant has a complaint about a research project in which he is participating or has participated.

E. Any participant who has a complaint about a research project in which he is participating or has participated shall be referred to the committee to determine if there has been a violation of the protocol.

F. The committee shall require reports from approved research projects at least annually to ensure conformity with the approved proposal. The frequency of such reports shall be consistent with the nature and degree of risk of each research project. The committee shall also require a report from the research project at the conclusion of the project.

3.3 Expedited Review

A. The committee is authorized to conduct an expedited review of a human research project which involves no more than minimal risk to the subjects if:

1. Another institution's or agency's human research review committee has reviewed and approved the project; or

2. The review involves only minor changes in previously approved research and the changes occur during the approved project period.

B. Each committee which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

3.4 Informed Consent

A. To conduct human research, informed consent of the participant or his legally authorized representative must be obtained, subscribed to in writing by the participant or his legally authorized representative and supported by the signature of a witness not involved in the conduct of research, except as provided for in subsections F and H of this section. If the participant is a minor otherwise capable of rendering informed consent, consent shall be subscribed to in writing by both the minor and his legally authorized representative.

B. A legally authorized representative may not consent to nontherapeutic research unless it is determined by the committee that such research will present no more than a minor increase over minimal risk to the participant.

C. An investigator shall seek such consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that assures absence of coercion or undue influence. The information that is given to the participant or the representative shall be in language understandable to the participant or the representative with regard to his educational level and language of greatest fluency.

D. No informed consent form shall include any language through which the prospective participant waives or appears to waive any of his legal rights, including any release of any individual, institution or agency or any agents thereof from liability for negligence.

E. Notwithstanding consent by a legally authorized representative, no person who is otherwise capable of rendering informed consent shall be forced to participate in any human research. In the case of persons suffering from organic brain diseases causing progressive deterioration of cognition for which there is no known cure or medically accepted treatment, the implementation of experimental courses of therapeutic treatment to which a legally authorized representative has given informed

consent shall not constitute the use of force.

F. The committee may approve a consent procedure which omits or alters some or all of the elements of informed consent set forth in 12VAC5-20-10, or waives the requirement to obtain informed consent provided the committee finds and documents that:

1. The research involves no more than minimal risk to the participants;

2. The omission, alteration or waiver will not adversely affect the rights and welfare of the participants;

3. The research could not practicably be performed without the omission, alteration or waiver; and

4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

G. Except as provided in subsection H of this section, the consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent required by 12VAC5-20-10. This form may be read to the participant or the participant's legally authorized representative, but, in any event, the investigator shall give either the participant or the representative adequate opportunity to read it before it is signed and witnessed; or

2. A short form written consent document stating that the elements of informed consent required by 12VAC5-20-10 has been presented orally to the participant or the participant's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the committee shall approve a written summary of what is to be said to the participant or the representative. Only the short form itself is to be signed by the participant or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary and a copy of the short form shall be given to the participant or the representative.

H. The committee may waive the requirement that the investigator obtain written informed consent for some or all participants if it finds that the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether he wants documentation linking him to the research, and the participant's wishes shall govern. In cases where the documentation requirement is waived, the committee may require the investigator to provide participants with a written statement explaining the research.

3.5 Categories of Human Research Exempt from Regulation

Research activities in which the only involvement of human participants will be in one or more of the following categories are exempt from this chapter:

A. The surveillance and investigation by the department into all preventable diseases and epidemics in the Commonwealth and into the means for the prevention of such diseases and epidemics conducted

pursuant to §32.1-39 of the Code of Virginia.

B. Research designed to study on a large scale anonymous vital records and registry data collected pursuant to the Code of Virginia, Chapter 7 (§32.1-249 et seq.) of Title 32.1 (Vital Records), §32.1-64.1 (Virginia Hearing Impairment Identification and Monitoring System), §32.1-69.1 (Viginia Congenital Anomalies Reporting and Education System), §32.1-70 (Statewide Cancer Registry), §32.1-71.l (Statewide Alzheimer's Disease and Related Disorders Registry), and §§32.116.1 and 32.116.1:2 (Emergency Medical Services Patient Care Information System).

C. Research or student learning outcomes assessment conducted in educational settings such as research involving:

1. Regular or special education instructional strategies; or

2. The effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods; or

3. The use of educational tests, whether cognitive, diagnostic, aptitude, or achievement, if the data from such tests are recorded in a manner so that participants cannot be identified, directly or through identifiers linked to the participants.

D. Research involving survey or interview procedures unless responses are recorded in such a manner that the participants can be identified, directly or through identifiers linked to the participants, and either:

1. The participant's responses, if they became known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to his financial standing, employability, or reputation; or

2. The research deals with sensitive aspects of the participant's own behavior such as sexual behavior, drug or alcohol use, or illegal conduct.

E. Research involving survey or interview procedures, when the respondents are elected or appointed public officials or candidates for public office.

F. Research involving solely the observation of public behavior, including observation by participants, unless observations are recorded in such a manner that the participants can be identified, directly or through identifiers linked to the participants, and either:

1. The observations recorded about the individual, if they became known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to his financial standing, employability, or reputation; or

2. The research deals with sensitive aspects of the participant's own behavior, such as sexual behavior, drug or alcohol use, or illegal conduct.

G. Research involving the collection or study of existing data, documents, records, or pathological specimens, if these sources are publicly available or if the information is recorded by the investigator

in a manner so that participants cannot be identified, directly or through identifiers linked to the participants.

3.6 Committee records

A. Documentation of committee activities shall be prepared and maintained and shall include the following:

1. Copies of all research proposals reviewed, scientific evaluations that may accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants;

2. Minutes of committee meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the committee; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution;

3. Records of continuing review activities;

4. Copies of all correspondence between the committee and the investigators;

5. A list of committee members;

6. Written procedures for the committee; and

7. Statements of significant new findings provided to participants.

B. The records required by this chapter shall be retained for at least three years, and records relating to research which is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized employees or agents of the department at reasonable times and in a reasonable manner.

PART IV. APPLICABILITY OF FEDERAL POLICIES

Human research at institutions which are subject to policies and regulations for the protection of human participants promulgated by any agency of the federal government shall be exempt from these regulations. Such institutions shall notify the commissioner annually by January 31 of their compliance with the policies and regulations of federal agencies. The commissioner shall identify institutions exempt from this chapter as reported in accordance with this section in the annual report to the Governor and the General Assembly.